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Sustainable Agriculture: Do GMOs Imperil Biosafety?

LAKSHMAN D. GURUSWAMY*

INTRODUCTION

Over 800 million people live on the verge of starvation, and a further 1.2 billion subsist on only \$1 a day.¹ Genetically modified organisms (GMOs) claim to offer a partial solution to this daunting challenge. The present article addresses a number of critical questions raised by this claim: To what extent might GMOs increase food production in developing countries?² More specifically, can GMOs help advance sustainable development (SD)³ and “sustainable agriculture” (SA)?⁴ These questions will be investigated within the framework of international environmental law and policy.

A number of skeins run through the answers offered in this article. The first among them deals with a brewing trade and environmental conflict. What is at issue here is the extent to which the restrictions on trade in GMOs, or living modified organisms (LMOs) as they are sometimes called, are consistent with SD. The World Trade Organization (WTO) and the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement)⁵ are part of the General

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1. United Nations Population Fund, *State of the World Population 2001*, cha. 2 (2001), <http://www.unfpa.org/swp/2001/english/ch02.html#2>.

2. More specifically, the present article will not address certain serious problems arising from this premise. Even if GMOs succeed in increasing the world's harvest, the almost intractable problems of poverty, inequity, and distribution will remain to be solved.

3. The terminology surrounding this subject calls for clarification and will be dealt with more fully in Part I. Despite the uncertainty surrounding its meaning, SD may be broadly perceived as economic and social growth that does not damage the environment and that meets the needs of the present without incapacitating future generations.

4. SA also possesses no canonical meaning and will be used in this article as an application of the principles of SD to agriculture.

5. Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1A, 69 (1994) [hereinafter SPS Agreement], available at http://www.wto.org/english/docs_e/legal_e/15-sps.pdf.

Agreement on Tariffs and Trade (GATT)⁶ regime institutionalizing free trade. To the extent that a decision to ban GMOs obstructs free trade, the SPS Agreement requires that such decisions be justified on principles of scientific risk assessment. The Biosafety Protocol (also known as the Cartagena Protocol)⁷, on the other hand, focuses on environmental protection, not free trade. The Biosafety Protocol allows nations pursuing biosafety to ban GMOs by using the precautionary principle, even where strict scientific proof may be lacking.

Second, any judicial dispute over this issue will fall within the jurisdiction of the Dispute Settlement bodies of the WTO, because neither the Convention on Biological Diversity (CBD) nor the Cartagena Protocol creates binding dispute settlement procedures. Environmentalists, including this author, have justifiably been suspicious about the judicial machinery of the WTO.⁸ To assuage such fears, it is necessary that any decisions taken by the judicial bodies of the WTO be based on the international customary law principles of fairness and reasonableness discussed more fully in Part VI.

Third, given the Janus-like character of SD referred to below and the fact that both the SPS Agreement and the Biosafety Protocol purport to advance SD, one must consider to what extent they actually do so. This question can satisfactorily be answered only through an examination of the real objectives (as distinct from the professed objectives), of the two instruments.

The article is divided into six parts. SD, as incorporated into international environmental law, is developed in Part I of the article. Following this, Part II describes the history and development of sustainable agriculture. Part III then incorporates these principles by highlighting the promise of GMOs, and showing the many benefits they can bring to modern agriculture. While GMOs have many advantages, Part IV addresses some of the concerns raised by opponents of GMOs. Given these concerns, Part V argues that scientific risk assessment strikes the right balance by providing a fair and reasonable basis for determining whether GMOs might cause health or biological damage. Part VI

6. General Agreement on Tariffs and Trade: Multilateral Trade Negotiations, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 1 (1994), 33 I.L.M. 1125 (1994) [hereinafter GATT].

7. Cartagena Protocol on Biosafety to the Convention on Biodiversity, Jan. 29, 2000, 39 I.L.M. 1027, (2000) [hereinafter Protocol].

8. See Lakshman Guruswamy, *The Promise of UNCLOS: Justice in Trade and Environmental Disputes*, 25 ECOLOGY L.Q. 189 (1998); Lakshman Guruswamy, *Should UNCLOS or GATT/WTO Decide Trade and Environmental Disputes?*, 7 MINN. J. GLOBAL TRADE 287 (1998) [hereinafter Guruswamy, *Should UNCLOS or GATT/WTO Decide*].

then discusses the extent to which the legal overlay of the SPS Agreement and the Biosafety Protocol incorporates these principles. It concludes that GMOs offer promise as instruments of SD and that the WTO legal regime is friendlier to SD and SA than the Biosafety Protocol.

I. SD⁹

The international community has accepted SD as the *grundnorm*¹⁰ of international environmental law since its adoption at the Earth Summit of 1992.¹¹ Despite its fundamental status, the concept of SD retains a chimerical character, and needs to be honed, refined, and more clearly defined. While the concept of SD continues to evolve, a recent restatement of SD, as conceptualized by a group including a significant number of Nobel Laureates, is worthy of particular attention.¹² This distinguished group defines SD as the wise use of resources through social, economic, technological, and ecological policies governing natural and human engineered capital.¹³ According to this re-statement, such policies should promote innovations that assure a higher

9. This section is based upon and reproduces segments of Lakshman Guruswamy, *Integration & Biocomplexity*, 27 *ECOLOGY L.Q.* 1191 (2001).

10. A *grundnorm*, translated in the United States as the basic norm, is the foundational premise or initial hypothesis conferring validity or legitimacy on all other norms of international environmental governance. As formulated by the Austrian jurist Hans Kelsen, it "is the postulated ultimate rule according to which . . . norms . . . are established and annulled, receive and lose their validity." HANS KELSEN, *GENERAL THEORY OF LAW AND STATE* 113 (1945); see also HANS KELSEN, *PURE THEORY OF LAW* 8, 194-95 (1967).

11. The United Nations Conference on Environment and Development (UNCED) or Earth Summit was convened in Rio de Janeiro, Brazil, in 1992. The Earth Summit was the biggest and most important environmental conference in history. It sought to give expression to sustainable development, and fulfill its goals of addressing the dual problems of environmental protection and socio-economic development, by producing two treaties: the Convention on Biological Diversity and the Framework Convention on Climate Change; two instruments: the Rio Declaration and Agenda 21; together with a non-binding declaration on Forest Principles. A more definitive restatement of SD will be attempted at the World Summit on Sustainable Development (WSSD) in Johannesburg September 2-11, 2002.

12. Inspired in part by UNCED and subsequent conferences and events, a collection of noted scientists, scholars, and policymakers determined to create a comprehensive and authoritative body of knowledge incorporating a unified, interdisciplinary understanding of the interdependence of natural and human-created systems. To this end, these visionaries initiated the Encyclopedia of Life Support Systems (EOLSS), a project currently under development. United Nations Educational, Scientific and Cultural Organization (UNESCO), EOLSS, *Conceptual Framework*, in *ENCYCLOPEDIA OF LIFE SUPPORT SYSTEMS* (2002), at <http://www.eolss.co.uk/CF.pdf>; see also 1 *OUR FRAGILE WORLD: CHALLENGES AND OPPORTUNITIES FOR SUSTAINABLE DEVELOPMENT* (M. K. Tolba ed., 2001) [hereinafter 1 *OUR FRAGILE WORLD*]; 2 *OUR FRAGILE WORLD*, *supra* [hereinafter 2 *OUR FRAGILE WORLD*].

13. See 1 *OUR FRAGILE WORLD*, *supra* note 12; 2 *OUR FRAGILE WORLD*, *supra* note 12.

degree of life support for the fulfillment of human needs while ensuring intergenerational equity.

One should begin an assessment of this preliminary definition with the acknowledgment that SD is a potentially self-contradictory concept, even though it has emerged as the dominant paradigm of international environmental law. SD is self-contradictory to the extent that it embraces two antithetical concepts: conservation and economic development. Conversely, SD may give expression to a classic Hegelian dialectic in which the dynamic clash of a thesis (development) and an antithesis (conservation and environmental protection) leads to the forging of a synthesis (SD). The extent to which SD expresses a satisfactory synthesis of two competing concepts will depend on whether it can satisfactorily mediate particular clashes between laws and policies, addressing environmental protection on the one hand and development on the other. One such potential conflict concerns trade in GMOs, or LMOs, and involves the competing international legal regimes of the GATT/WTO and the SPS Agreement versus the Biosafety Protocol under the CBD.

The definition of SD just offered creates a significant change in one's understanding of ecology (a world view based on the principles of ecology) and national and international approaches to environmental protection. For instance, during the 1960s and 1970s, environmental activists were mainly concerned with preserving endangered species and safeguarding natural resources from human depredation. Humans were generally cast in the role of predators, parasites, and wrongdoers. SD, on the other hand, embraces *human welfare* as a central objective, while simultaneously pursuing conservation,¹⁴ or ecology. This definition of SD recognizes the necessity of human interaction with the natural world. Such interaction is consistent with the non-equilibrium paradigm in ecology. The non-equilibrium model integrates humans into the natural world and allows for appropriate human intervention into natural systems in an effort to maximize life support systems.¹⁵ It is therefore opposed to the equilibrium model that calls for preservation of the natural world through the exclusion, or limited intervention, of humans.

It is now well-known that ecological systems do not possess fixed equilibrium, or static stability, but are instead characterized by change.¹⁶ Such

14. See Sir Shridath Ramphal, *Sustainable Development*, in *ENCYCLOPEDIA OF THE ENVIRONMENT* 680 (Ruth A. Eblen & William R. Eblen eds., 1994) [hereinafter *ENCYCLOPEDIA*].

15. See Ruth A. Eblen & William R. Eblen, *Preface*, in *ENCYCLOPEDIA*, *supra* note 14, at xv.

16. See Daniel B. Botkin, *Ecological Stability*, in *ENCYCLOPEDIA*, *supra* note 14, at 164, 164-66.

a view sees nature in a constant state of flux, and stands in marked contrast to the earlier belief that ecological systems exist in a perfectly balanced, or stable, state. Not surprisingly, a significant number of environmental lawyers and policy makers have been weaned on the earlier view, which prevailed in the 1960s and 1970s, and they believe that law and policy should strive to restore and maintain the primordial balance of nature. Thus, much of the bedrock legislation such as the Endangered Species Act,¹⁷ the Wilderness Act,¹⁸ the National Environmental Policy Act of 1969 (NEPA),¹⁹ section 404 of the Clean Water Act,²⁰ and the broader non-degradation provisions of the Clean Air²¹ and Clean Water Acts²² are based on the premise that nature is best protected when it is left untouched. According to the equilibrium view, attempting to restore nature to a previous state free of human intrusion would enable nature to achieve a natural permanence of form and structure that would persist indefinitely.²³

In contrast to the equilibrium view, the non-equilibrium paradigm recognizes that living things and the external world are not separate static entities, but are interacting components of complex, dynamic systems. Today, ecologists recognize that humans and their environments are interacting components of these systems, and that practically all inhabited environments have been profoundly altered by human cultures.²⁴ Human life necessarily implies interventions in nature; however, if managed in accordance with available knowledge, these interventions can be ecologically sound and actually create new environmental values.²⁵ An important aspect of this viewpoint is that the old adage "nature knows best" is not always true: nature often creates ecosystems that are inefficient, wasteful, and destructive. Thus, the non-equilibrium perspective proposes that by using reason, knowledge, imagination, and toil, people can shape ecosystems that have more efficient qualities than nature could achieve.²⁶ Such a re-configured ecological foundation is more

17. Endangered Species Act, 16 U.S.C. §§ 1531-1544 (1994).

18. National Wilderness Preservation System, 16 U.S.C. §§ 1131-1136 (1994).

19. National Environmental Policy Act of 1969 (NEPA) § 2, 42 U.S.C. §§ 4321-4347 (1994).

20. Federal Water Pollution Control Act § 404, 33 U.S.C. § 1344 (1994).

21. Air Pollution Control Act § 101, 42 U.S.C. § 7401 (1994).

22. Federal Water Pollution Control Act § 101, 33 U.S.C. § 1251 (1994).

23. See A. Dan Tarlock, *The Nonequilibrium Paradigm in Ecology and the Partial Unraveling of Environmental Law*, 27 LOY. L.A. L. REV. 1121 (1994); Jonathan Baert Wiener, *Law and the New Ecology: Evolution, Categories, and Consequences*, 22 ECOLOGY L.Q. 325 (1995).

24. Eblen & Eblen, *supra* note 15, at xv.

25. *Id.* at xv-xvi.

26. See Rene Dubos, *Humanized Environments*, in *ENCYCLOPEDIA*, *supra* note 14, at 342, 344.

open to the role of science and knowledge, and the adaptation of nature to meet human needs. It can significantly affect the way SD and the role of GMOs are viewed.

II. SA

Sustainable agriculture applies the principles of SD to agriculture. The word "sustain," from the Latin *sustinere* (*sus*, from below and *tenere*, to hold), implies long-term support or permanence. As it pertains to agriculture, sustainable describes farming systems that are "capable of maintaining their productivity and usefulness to society indefinitely. Such systems . . . must be resource-conserving, socially supportive, commercially competitive, and environmentally sound."²⁷ SA must be placed within the broader context of food production and agriculture. Because population is growing at the exponential rate of 1.4 percent per year,²⁸ total world agricultural yield will have to increase significantly over the next several generations to meet this additional demand. If current calorie consumption levels are maintained, this will require a doubling of agricultural production over the next fifty years.²⁹ In reality, there are only two ways to increase production—expand the area tilled or increase yield per unit. There are obvious limits to both methods, but the costs of expanding the area tilled are enormously greater than those of

27. Richard Duesterhaus, *Sustainability's Promise*, J. SOIL & WATER CONSERVATION, Jan.-Feb. 1990, at 4 (quoting John Ikerd). "Sustainable agriculture" was addressed by Congress in the Food, Agriculture, Conservation, and Trade Act of 1990, Pub. L. No. 101-624, 16 Stat. 1603 (1990) [hereinafter Farm Bill], available at <http://wsare.usu.edu/fbill90/title16.htm>. Under the Farm Bill,

The term "sustainable agriculture" means an integrated system of plant and animal production practices having a site-specific application that will, over the long term—

- (A) satisfy human food and fiber needs;
- (B) enhance environmental quality and the natural resource base upon which the agricultural economy depends;
- (C) make the most efficient use of nonrenewable resources and on-farm resources and integrate, where appropriate, natural biological cycles and controls;
- (D) sustain the economic viability of farm operations; and
- (E) enhance the quality of life for farmers and society as a whole.

7 U.S.C.A. § 3103(17) (1999).

28. United Nations Population Fund, *State of World Population 2001*, <http://www.unfpa.org/swp/2001/english/ch02.html#2> (last visited Apr. 26, 2002). Even the revised forecasts project that population will rise to 9 billion by 2070. Wolfgang Lutz et al, *The End of Population Growth*, NATURE, Aug. 2, 2001, at 543.

29. John H. Barton, *Biotechnology, the Environment, and International Agricultural Trade*, 9 GEO. INT'L. ENVTL. L. REV. 95, 98 (1996); Gurdev S. Khush & Mahabub Hossain, *Technologies for Increasing Food Production*, in 1 OUR FRAGILE WORLD, *supra* note 12, at 599.

increasing yield.³⁰ SA calls for the growth of more food in a manner that is sustainable.

Agriculture, or the cultivation of plants for food, has been practiced for thousands of years. After the domestication of cereal grains, humans intuitively recognized degrees of genetic variation and excellence among the plants in their field. As a result, they saved seeds from the best plants for future years' crops. They also cross-fertilized plants to achieve better results and to create crops that would bear more fruit. For example, the

ancient Babylonians knew that pollen from the male date palm tree must be applied to pistils from a female tree to produce fruits. Rudolph Joseph Camerarius showed that the same is true of corn (maize). Carlus Linnaeus and Josef Gottlieb Kolreuter, in a series of work published from 1761-1798, described crosses and varieties.³¹

This led Gregor Mendel, in 1866, to formulate his celebrated rules, and to found the theory of the gene.³² However, the impact and import of Mendel's work was not discovered for many years to come.

Beginning about the middle of the twentieth century, scientific plant breeders recognized the laws of genetic inheritance and began to apply them to the improvement of plants. One of the most important discoveries made during the short history of scientific breeding is the existence of an enormous wealth of genetic variability among the plants of the world. Scientific breeders seek to harness these genetic resources, libraries, or banks to improve the desirable characteristics of plants.³³ For example, they attempt to introduce desirable new genes into an existing plant to achieve herbicidal, insect, frost, or drought resistance. This process is known as genetic engineering.

Historic plant breeding methods, based on genetics, used cross breeding and plant and seed selection to achieve more desirable results. The plant breeder usually tries to create an ideal plant that combines a maximum number of desirable characteristics. These qualities may include resistance to diseases

30. Barton, *supra* note 29, at 99; Gurdev S. Khush & Mahabub Hossain, *Technologies for Increasing Food Production*, in 1 OUR FRAGILE WORLD, *supra* note 12, at 599.

31. 19 ENCYCLOPEDIA BRITANNICA 700 (2002).

32. *Id.*

33. *See id.* at 98; Ralph Kirby, *Biological Science Foundations*, in 2 OUR FRAGILE WORLD, *supra* note 12, at 1127, 1135.

and insects, tolerance to heat and frost, ease in growth, optimum size, greater yield, and better quality.³⁴ Consequently, most present-day varieties of domestic or agricultural plants are so modified from their wild progenitors that they are no longer able to survive in nature. Indeed, in some cases, the cultivated forms are so different from their wild predecessors that they defy identification according to ancestry.

Many view the introduction or transfer of new genes into an organism as a more precise and scientific extension of long and costly historic agricultural practices. Others, however, are suspicious of the incredible speed of genetic modifications. Genetic modifications that might have taken decades under traditional breeding practices are now being replaced by GMOs that can be created in a few years.³⁵

Biotechnology, it is argued, provides a promising means to increase the yields derived from existing farmed acreage, an attractive alternative to expanding operations into uncultivated lands.³⁶ Genetically modified crops may well offer lower-cost products that taste good, are easy to transport, have increased shelf life and better nutritional value, and pose as yet no clearly demonstrated health or safety concerns.³⁷ Furthermore, by breeding and engineering plants to be pest-resistant and by choosing and improving biological predators, technology can reduce the need for pesticides. Technology can also provide better foods by reducing post-harvest crop loss to vermin and rodents and by improving nutritional quality.³⁸ Critics, however, see perils in so speedily transferring foreign genes that were not previously present in a species, as they are likely to create unpredictable physiological or biochemical effects. Although the first genetically engineered foods first appeared on the market just years ago, approximately thirty to thirty-five percent of soybeans and twenty-five percent of corn grown in the United States in 1998 were from genetically-modified seeds, with total acreage in genetically modified crops exceeding thirty million.³⁹ Furthermore, about sixty percent of

34. 19 ENCYCLOPEDIA BRITANNICA, *supra* note 31, at 98; Horst Doelle, *Biotechnology*, in 2 OUR FRAGILE WORLD, *supra* note 12, at 1591, 1594-96.

35. STEPHEN NOTTINGHAM, EAT YOUR GENES: HOW GENETICALLY MODIFIED FOOD IS ENTERING OUR DIET 5-6 (1998).

36. Julie Teel, *Regulating Genetically Modified Products and Processes: An Overview of Approaches*, 8 N.Y.U. ENVTL. L.J. 649, 650 (2000); *see also* Barton, *supra* note 29, at 99.

37. Teel, *supra* note 36, at 653.

38. Barton, *supra* note 29, at 99-100.

39. Teel, *supra* note 36, at 649.

packaged foods available in supermarkets contain GMOs.⁴⁰ It is necessary to consider, albeit briefly, these competing claims.

III. THE PROMISE OF GMOS

Biotechnology and GMOs offer new opportunities for significantly increasing the productivity of agriculture, reducing the cost of food production, and decreasing the environmental damage caused by modern agricultural practices.⁴¹ A point that is of particular application to developing countries is the capacity of information intensive industries, such as biotechnology, to substitute information for materials, energy and associated wastes, and to focus on increasing products or services without increasing industrial throughput. The biotechnology field is able to do this by providing industries and techniques that substitute for the extraction, pollution, and trade of energy-intensive natural resources. This is not to claim that it does so in every case, but rather that there are a number of key contributions worth mentioning. These include:

1. Producing more food on the same area of land, thus reducing pressure to expand into wilderness, rainforest, or marginal lands;
2. Reducing post-harvest loss of food, while improving the quality of fresh and processed food, thus boosting the realized nutritional yield per acre;
3. Displacing resource- and energy-intensive inputs, such as fuel, fertilizers, and pesticides, thus reducing unintended impacts on the environment and freeing those resources to be used for other purposes or conserved for the future.

40. *Id.*

41. Robert B. Horsch & Robert T. Fraley, *Biotechnology Can Help Reduce the Loss of Biodiversity*, in PROTECTION OF GLOBAL BIODIVERSITY: CONVERGING STRATEGIES 49 (Lakshman D. Guruswamy & Jeffrey A. McNeely eds., 1998).

4. Encouraging reduction of environmentally damaging agricultural practices, and adoption of sustainable practices, such as conservation tillage and encouraging integrated pest management.⁴²

The achievements of agricultural genetic engineering thus far include crops that resist herbicides, insects, virus, fungal, and nematodes. The list extends to include plants that photosynthesize and fix nitrogen, and that are more tolerant to salinity, drought, frost, and other greater yielding varieties.⁴³

A. Herbicide Resistant Crops

Weeds compete with crops for moisture, nutrients, and light. Therefore, uncontrolled weed growth can lead to large losses in crop yield.⁴⁴ The large and sometimes indiscriminate use of herbicides to control weeds is a fact of agricultural life. Unfortunately, broad spectrum herbicides that are effective against weeds also kill or harm cultivated crops. Moreover, they continue to damage crops that are later grown in soil onto which these pesticides have been sprayed.

Most herbicides are gradually broken down in the field by soil bacteria. Agricultural scientists have successfully transferred these detoxifying genes from the soil bacteria to transgenic plants, so that the plants themselves can break down the deleterious effects of herbicides. They have also succeeded in transferring genes from plants that are naturally resistant to herbicides to other plants that are susceptible to pests. Herbicide resistant varieties of maize, canola, oilseed rape, sugar, beet, tobacco, and cotton are now available.⁴⁵ Herbicide resistant crops could prevent crop loss, while leading to a more efficient and effective use of herbicides. They could further reduce herbicide use by eliminating pre-crop spraying against weeds, and allowing herbicides to be sprayed only after the crop has emerged—something that may not be possible with ordinary unmodified crops.⁴⁶

42. *Id.*

43. *Id.*

44. According to the FAO, diseases, insects, and weeds cause crop loss of 25% in rice and other food grains.

45. NOTTINGHAM, *supra* note 35, at 6.

46. Khush & Hossain, *supra* note 29, at 605.

B. Insect Resistant Crops

In the final chapter of *Silent Spring*, Rachel Carson saw *Bacillus thuringiensis* (B.t.) sprays and biological controls as a way of avoiding environmentally damaging insecticides such as DDT.⁴⁷ B.t. is a soil bacterium that is fermented to create a commercial insecticide (B.t. spray) that is biodegradable and safe for humans and non-target organisms. Genes expressing B.t. toxins have been engineered into a number of plants including tobacco, potatoes, maize, and cotton. Another approach inserts genes into organisms that are naturally insecticidal to make them efficient as insect pathogens. In India, the coffee berry borer has been contained.⁴⁸ The United States Environmental Protection Agency (EPA) has granted permission for field testing of baculovirus incorporating a scorpion toxin gene to protect tobacco, cabbage, cotton, broccoli, and lettuce.⁴⁹

The benefits of insect-resistant crops are numerous. Developing a GMO costs much less than producing a new chemical. According to an early estimate, inventing, developing and registering a new chemical in 1989 would have cost \$25 million, while the cost of developing a new crop variety may be under \$1 million.⁵⁰ The use of spraying would be reduced, creating additional ecological benefits. Human health would benefit in that the numbers of spray operators exposed to toxic sprays would be reduced. This would be especially advantageous in developing countries, where inadequate training of operators creates significant health problems.⁵¹

C. Modified Fruits and Vegetables

Nottingham notes that tomatoes have been genetically modified so as to enable vine-ripe picking. Ripe tomatoes picked off the vine retain their taste and flavor better than force-ripened or transit-ripened fruit. Moreover, they still possess substantial shelf life. The same has been done with cantaloupes. Potatoes have been starch enhanced so that they absorb less fat when fried, while high sweetness strawberries are on their way. Many developments can be beneficial to human health, such as vegetable oils that have been modified by

47. See RACHEL CARSON, *SILENT SPRING* (1962).

48. Khush & Hossain, *supra* note 29, at 612.

49. NOTTINGHAM, *supra* note 35, at 61.

50. R.L. Meeusen & G. Warren, *Insect Control with Genetically Engineered Crops*, 34 ANN. REV. ENTOMOLOGY 373 (1989).

51. NOTTINGHAM, *supra* note 35, at 54-55.

changing their fat balance. This diminishes saturated fats, and creates more polyunsaturated fats.⁵² These developments offer great promise, as they avoid spoilage and conserve water during storage. They could be of particular benefit to third world countries that lack access to fresh fruit and adequate refrigeration facilities.

Furthermore, one of the deficiencies of a pure vegetarian diet is that plant seed proteins lack essential amino acids, in contrast to animal protein. Scientists have corrected the lack of essential amino acids in plants by manipulating them to supply all the essential amino acids in one transgenic food.⁵³

D. Resistance to Viral and Fungal Diseases and Nematodes

Viral diseases cause economic damage in most agricultural crops, and there are no chemical viricides that do not also harm the crop. Now anti-viral protein genes have been engineered that will protect potato, sweet potato, papaya, alfalfa, cucumber, cantaloupe, and squash against particular viral diseases. Fungi attack a number of major crops, for which the usual treatment is to spray fungicides. Anti-fungal genes that might obviate or reduce fungal attacks are currently being developed.

Nematodes are parasitic roundworms that cause enormous crop damage, estimated at \$100 billion annually.⁵⁴ One of the most effective fumigants, methyl bromide, is being phased out or banned in many countries because it damages the ozone layer.⁵⁵ Scientists are now producing transgenic sugar beet varieties expressing a wild beet gene that possesses nematode resistance. Such developments could be of significant benefit to developing countries that cannot afford the cost of nematicide treatments that do not contain methyl bromide.⁵⁶

52. *Id.* at 64-67.

53. *Id.*

54. *Id.* at 72.

55. *Id.* at 72.

56. *Id.* at 71-73.

E. Tolerance to Salinity, Drought, and Frost

Salinity, drought, and frost pose significant problems in regions that might otherwise be fertile agricultural areas⁵⁷ and thus severely reduce agricultural output. Many varieties of food plants are not naturally tolerant to salinity, drought, or frost. Scientists have been able to genetically manipulate plants to make them tolerant to salinity, drought, and frost, while still retaining high yields. Transgenic plants, such as rice, salt-tolerant tomato, melon, and barley varieties are among some of the plants being genetically modified in this manner.⁵⁸

F. Drugs, Vaccines, Photosynthesis, and Nitrogen Fixation

Three new developments involving GMOs may prove to be of great importance. First, transgenic crops may integrate genes expressing therapeutic drugs or vaccines. For example, bananas or rice could provide an accessible source of medical drugs in the developing world, and a wide-range of vaccines are being produced in bananas, cowpeas, and other crops.⁵⁹

Second, improving the efficiency of photosynthesis is one of the crop transformations that could have the greatest impact on the world food supply. Photosynthesis is the natural process used by green plants to synthesize organic compounds from carbon dioxide and water, using energy from sunlight harnessed by chlorophyll molecules. Some plants, referred to as C₄, photosynthesize more effectively than others, called C₃. Research programs are attempting to transfer the more effective C₄ genes to C₃ plants.⁶⁰

The third process can extend the ability of plants to fix nitrogen, as nitrogen is essential for all plant growth.⁶¹ While nitrogen is the most abundant gas in the world, it is not absorbed from the air by most plants. Leguminous plants are the exception, because nitrogen fixation occurs in their root nodules. Experiments now underway seek to improve the efficiency of such leguminous

57. Salinity is becoming a major water quality problem. Salinity levels in the West of the United States have worsened significantly. JOSEPH L. SAX ET AL., *LEGAL CONTROL OF WATER RESOURCES* 17 (2d ed. 2000). The Colorado River Basin Salinity Control Act, 43 U.S.C. § 1592 (1974), responds to some of the salinity problems of the Colorado River.

58. Tomatoes, for example, do this by drawing the salt into their leaves and not the fruit. John Travis, *Gene Makes Tomatoes Tolerate Salt*, 160 SCI. NEWS 68 (2001), available at 2001 WL 8796383.

59. NOTTINGHAM, *supra* note 35, at 77-78.

60. *Id.* at 73-74.

61. Toni A. Voelker et al., *Fatty Acid Biosynthesis Redirected to Medium Chains in Transgenic Plants*, 257 SCIENCE 72, 73 (1992).

plants and to inoculate the soil surrounding other plants with a nitrogen fixing bacterium.⁶² Benefits of resistance to viral and fungal diseases are not much different than medical vaccinations for humans. GMOs are attempts to make crops stronger and healthier.

IV. POSSIBLE PITFALLS

A. *Industrial Agriculture*

To the extent that GMOs offer ways of making “industrial agriculture” more productive, it is relevant to consider the criticisms leveled against this kind of agriculture. According to some critics, industrial agriculture views the farm as a factory receiving inputs such as pesticides, feed, fertilizer and fuel, and producing outputs of crops and livestock. The goal is to increase yield and decrease costs of production, usually by employing economies of scale.⁶³ Industrial agriculture relies on monoculture, or the cultivation of one crop at a time in a field, resting on a narrow genetic base, and is heavily dependent upon pesticides and fertilizer. This has resulted in a severe decline in genetic diversity.⁶⁴

Even before the advent of GMOs, agriculture probably adversely affected the natural environment more than any other industry. The expansion of agriculture and commercial harvesting has led to the destruction of forests and the conversion of natural habitat to cropland. Industrial agriculture, which uses fewer varieties of plants to increase productivity, has led to the loss of biodiversity and increased susceptibility to pests. Critics also point out that industrial agriculture relies heavily on fossil fuels. They calculate that when transportation, preparation, and processing costs are figured in, the energy balance is 9.8 kilocalories (kcal) of fossil energy per kcal of food energy.⁶⁵ Moreover, compaction, salinization, the decline of organic matter and degradation of the soil’s physical structure caused by industrial agriculture has resulted in soil erosion and the deterioration of soil quality.⁶⁶

62. NOTTINGHAM, *supra* note 35, at 73-74.

63. See Union of Concerned Scientists, *Industrial Agriculture: Features and Policy*, at <http://www.ucsusa.org/food/id.ag.htm> (last modified Mar. 2001).

64. *Id.*

65. Laura L. Jackson, *Agricultural Industrialization and the Loss of Biodiversity*, in PROTECTION OF GLOBAL BIODIVERSITY: CONVERGING STRATEGIES, *supra* note 41, at 69.

66. *Id.* at 69-70.

Consequently, agricultural trade is quickly becoming a central element of conflict over international environmental practices.⁶⁷ International law and national law have responded to this challenge by placing restrictions on international trade in order to protect nations from the adverse impacts of agriculture. Thus, “phytosanitary” laws protect against plant pests and diseases, while “epizootic” laws are aimed at animal diseases or pests. In addition, there are laws protecting consumers against pesticide residues in imported foods.⁶⁸

B. Biotechnology

Reservations about the use of biotechnology compound the criticisms leveled against industrial agriculture. They arise from the unresolved uncertainties surrounding the environmental and health implications of an often untested and ever-expanding range of GMOs. However obvious the advantages of GMOs might appear to its proponents, the disadvantages and hidden costs of new technologies are equally obvious to its opponents.

For example, while the immediate benefits of greater yields are tangible, the longer-term consequences of an increase in pest-resistant crops may be less evident.⁶⁹ Critics of herbicide-resistant crops claim that these crops could themselves become weeds in other crops, while related weedy species could acquire the resistance through pollen transfer from transgenic crops. They also argue that herbicide-resistant crops are likely to increase the amount of potentially hazardous herbicide sprayed into the environment. If that were to happen, these herbicides could have adverse effects on natural habitats and soils, leading to more herbicide resistant plants, as well as to disease-causing fungus and bacteria.⁷⁰ Using GMOs without further knowledge of their effects may be a more serious threat to our ecosystems and biodiversity than the risks of not using GMOs.⁷¹

Genetic diversity may also suffer in the search for beneficial genes. Temporal considerations govern human views of beneficial genes and, without the benefit of hindsight, may irrevocably interfere with the library of genes in their natural state. For example, through human engineering efforts, the wild

67. Barton, *supra* note 29, at 95.

68. *Id.* at 97.

69. Randall S. Abate & Gretchen L. Gatson, *The Biosafety Protocol and the World Trade Organization: Can the Two Coexist?*, 12 PACE INT'L. L. REV. 107, 118 (2000).

70. NOTTINGHAM, *supra* note 35, at 43-44.

71. Teel, *supra* note 36, at 650.

beet gene that possessed nematode resistance was lost in the domestic version. This gene may never have been “created” or found without the wild plant, since domestic varieties did not contain the resistant gene.⁷²

There is also evidence that beneficial insects, “unintended targets,” are killed as a result of GMOs containing pesticides. A recent and controversial Cornell University study concluded that pollen from *Bt*-corn can kill Monarch butterfly larvae.⁷³ This could result in serious ecological imbalance. Moreover, the existence of herbicide-resistant crop such as Round-up Ready soybeans will surely increase the use of such herbicides on crops. The fact that a crop is resistant to an herbicide will mean that farmers will spray more herbicides to kill weeds, secure in the knowledge that such herbicides will not harm their crop.⁷⁴ This could result in increased contamination of food and water supplies.⁷⁵

One commentator points to the harm caused by horizontal gene transfer from genetically modified sugar beet to the bacteria and yeast in the gut of baby bees. He also discusses how GM crops are not actually solving pest problems but encouraging new resistant pests to evolve.⁷⁶ Others fear a Frankenstein evolution or creation of a “killer gene” or “killer weed”—an undesirable plant that is resistant to any method of human control or extermination. According to yet others, GMOs may affect human health by causing or aggravating food allergies. Food allergies are an adverse reaction to an otherwise harmless food that involves an abnormal response of the body’s defenses. Some experts believe that in the future proteins will be coming into food crops not just from known sources of common allergens such as peanuts, shellfish and dairy but from plants of all kinds, bacteria and viruses whose potential allergens are uncommon or unknown.⁷⁷

Apart from these largely utilitarian or extrinsic arguments about GMOs, it is possible to formulate an inherent or intrinsic theological case against

72. *Id.*

73. *Id.* at 657.

74. See Andrew Pollack, *Biotech Crop Has Mystery: Extra DNA*, DEN. POST, Aug. 16, 2001, at 21A, available at 2001 WL 6759834.

75. Abate & Gateson, *supra* note 69, at 119.

76. See Dr. Mae-Wan Ho, *Can Biotechnology Help Fight World Hunger?*, THIRD WORLD NETWORK (JUNE 29, 2000), available at <http://www.twinside.org.sg/title/hunger.htm>.

77. Consumer’s Choice Council, *Re: GMOs/LMOs and Labeling in the Context of the Biosafety Protocol Negotiations* (citing Marion Nestle, *Allergies to Transgenic Foods: Questions of Policy*, 334 NEW ENG. J. MED. 726, 726-27), available at <http://www.consumersunion.org/food/gmoscpi799.htm> (last visited Feb. 8, 2002).

biotechnology. Such a religious case is premised on deistic belief and posits that shifting genes around between species, or between individuals and species, is tantamount to arrogating a power that should be exercised only by the Creator. On this view, humans ought not to aspire to infinite knowledge, and power and bioengineering is an attempt to usurp God's dominion.

C. Answering the Critics

There are answers to these criticisms. However, the answer to the question as to whether GMOs constitute a threat to biosafety should be determined on a case-by-case basis after a scientific risk assessment. In this section, therefore, I offer only a distillation of these answers as a guide to the fully argued cases made by both sides to this dispute.

First, GMO proponents counter that problems leading to the development of weeds and ecosystem disruption are as likely, if not more likely, to arise with the introduction of non-genetically modified exotic species that lack natural predators in the new environment.⁷⁸

Second, as to the fear of allergies, the FAO and WHO have called for more rigorous pre-testing to prevent GMOs from triggering allergies.⁷⁹ In fact, possible allergenic effects of GMOs have been discovered as a result of the pre-release testing undertaken by biotechnology companies⁸⁰ who also have voluntary risk management policies.⁸¹

Third, it has now been documented by field tests that the monarch butterfly is not, in fact, affected by B.t. corn.⁸² Finally, it is more accurate to think of humans as partners or instruments of God in achieving good. Humans have studied nature as part of God's laws, and in order to understand more of God's nature. They have acted as his instruments in using and adapting nature over the millennia. Biotechnology is not doing anything fundamentally different to what humans have been doing on God's earth.

78. There is an exotic plant that is toxic to cattle that now grows wild in the West. See Teel, *supra* note 36, at 653.

79. See Business Line, *FAO Norms for Testing GMO FOOD Allergy*, available at <http://www.blonnet.com/businessline/2001/04/16/stories/071603s7.htm> (Apr. 16, 2001).

80. Consumer's Choice Council, *supra* note 77. This letter refers to the tests done by the Pioneer Hi-Bred International seed company that revealed how engineered soybeans reacted with the IgE of individuals with a Brazil Nut allergy.

81. Teel, *supra* note 36, at 653.

82. *New Studies Suggest That Bt Corn Has Little Harmful Effect on Butterflies*, 24 INT'L ENV'T REP. 845, 845 (2001) (summarizing 6 studies published by the National Academy of Sciences).

One insightful commentator has offered an arresting viewpoint. He asserts that many of the fears surrounding GMOs have been generated by non-governmental organizations (NGOs) that are pursuing their own interests regardless of the veracity of the claims they make. He states: "They discover that funding comes with notoriety. Their group must be in the news. Name recognition, just as in the business world, has real financial value. Foundation grants, private individual donations and government subsidies come with notoriety."⁸³ He continues that in the case of GMOs, these NGOs partner with organic farmers and whole foods retail chains, as well as foreign companies and countries who do not have, and do not want to pay for, U.S. technology. He concludes that many of the claims they make about GMOs are erroneous, false and unsubstantiated.⁸⁴

This article argues that GMOs do pose hazards and risks, but that hazards are not the same as risks, and that risks have are often countervailed by other risks. The answer to the question whether the hazards and/or risks posed by GMOs so outweigh their benefits as to impose restrictions on free trade should be found within the framework of risk assessment. It is to that analytical framework that we now turn.

V. STRIKING A BALANCE

Risk is an endemic part of human life, and the fact that GMOs, like a host of new substances or products, pose new risks does not confront us with a bizarre or outrageous new exigency. Risk forms part of the woof and warp of our modern lives. Moreover, it is well established that attempts to reduce identified risks can give rise to other risks.⁸⁵

Graham and Wiener give multiple examples of this risk versus risk tradeoff.⁸⁶ The ban on the fungicide EDB removed its cancer risk, but may have left grains and nuts with fungus-promoting aflatoxins that are more carcinogenic than EDB. The ban on cyclamates (artificial sweeteners) on the grounds that they are carcinogenic may increase consumption of sugar that could create particular risks for diabetics. The ban on ocean dumping of industrial wastes may have encouraged incineration on land closer to human

83. Dale Oesterle, *A Clear-headed Look at NGOs*, 13 COLO. J. INT'L ENVTL. L. & POL'Y 129, 130 (2002).

84. *Id.*

85. See generally RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT 1-41 (John H. Graham & Jonathan Baert Wiener eds., 1997).

86. *Id.* at 13-15.

beings and fragile freshwater ecosystems. Policies to stop chlorination of drinking water in order to reduce the risk of cancer may increase the risk from microbial water-borne diseases. The largest outbreak of cholera in recent history that killed 7,000 and affected more than 800,000 in Peru may have been due to the Peruvian government's decision to cease chlorinating its drinking water. This was spurred by U.S. risk assessments classifying chlorination as carcinogenic.

A rational decision as to whether or not to accept a risk is usually made after one has undertaken some kind of qualitative and/or quantitative analysis that balances the pros and cons of a risk. Most risks carry costs as well as benefits. While some of these may be quantified, others do not conform to such a calculus. Nonetheless, whether quantified or not, one may decide to accept a risk despite its costs because of its superior benefits, or reject another despite its benefits in light of its higher costs. One may, for example, accept the benefits of vaccination, air and car travel, and chemical additives in food and drinks, despite their risks or costs.

In undertaking this balancing process, this article rejects a once popular view that greatly exaggerated the impact of environmental risks. According to that view, the potential costs of environmental risks are great while the benefits are only modest. Accordingly, one should strive to avoid false negatives (conclusions that something is harmless) and accept false positives (erroneous conclusions that something is harmful).⁸⁷ It is now known that almost any human activity creates environmental risks and that false positives that deny society a useful product such as a vaccine can be as damaging as false negatives about a potentially harmful pollutant.

A. Scientific Risk Assessment

Risk assessment (RA) attempts to understand and estimate the likelihood of some type of adverse outcome resulting from an activity or product. The analysis is undertaken within the frameworks of two concepts: hazard and exposure. RA begins with research and data. The credibility and value of the assessment is directly related to the quality and quantity of data available about the product, the environment in which it will be used, and the population involved. Having obtained the necessary data, RA proceeds to estimate, assess,

87. See generally Talbot Page, *A Generic View of Toxic Chemicals and Similar Risk*, 7 *ECOLOGICAL* L. Q. 207 (1978). A false negative is an erroneous conclusion that something is harmless, while a false positive is an erroneous conclusion that something is harmful.

and characterize hazard and exposure in quantitative terms. RA then gives way to risk management: a process of decision-making that integrates the scientific findings of RA within the broader structure of policy and law.

The research and assessment process concerned with hazard recognizes that each activity or product has a certain degree of hazard or danger associated with it. Activities such as swimming, driving a car, or plowing a field may harm those involved; similarly, the use of any product, from commercial foodstuffs to a computer, has a probability of adverse effects on humans or the environment.

As it pertains to GMOs, hazard identification usually occurs in two stages. It begins by ascertaining the inherent or associated nature of a hazard. For example, the polio virus is extremely hazardous, whereas brewer's yeast is considered benign under almost any circumstances. Consequently, the question that arises is where on the hazard chart a candidate GMO should be placed. Thus, step one is identification of the specific adverse effect(s) associated with a product or activity.⁸⁸ The next stage in hazard identification assesses the likelihood or probability that harm will occur and the consequences or damage that might result.⁸⁹ The likelihood of the hazard being expressed or manifested will depend on the way it is handled or contained. For example, even the highly publicized anthrax bacteria can be handled without risk in special facilities.

The hazard component of risk assessment is then related to the level of exposure based on how often one engages in the particular activity or comes into contact with a particular product. Central to exposure is identification of the exposed population. For example, some activities, such as crossing a street, are more common, individualized, and short-lived than others. Similarly, some chemicals are highly labile and will not persist in the environment. On the

88. When there is a paucity of information about the hazardous nature of a substance or organism, it is necessary to gather as much information as possible and then, on a case-by-case basis, attempt to formulate a risk assessment. The information requirements are very similar in all OECD countries. Basically, the data required will include: Parent organism (taxonomy, molecular biology, physiology, reproduction); transgenic organism (molecular biology, reproduction); method of transgenesis; method, amount, and frequency of introduction; fate of transgene (transport, reproduction, transfer, establishment); toxicity of transgene products and intermediary metabolism; effective dose for toxicity; susceptible non-target organisms; effect on non-target organisms; and site characteristics and ecological effects.

89. The Presidential and Congressional Commission on Risk Assessment and Risk Management in the United States has been examining a framework for Environmental Health Risk Management. In their reports, published in January 1997 and April 1997, they have produced a framework in which risk management will be conducted by the U.S. Government. PRESIDENTIAL & CONG. COMM'N ON RISK ASSESSMENT & RISK MANAGEMENT IN REGULATORY DECISION-MAKING, 1 FINAL REPORT (1997); PRESIDENTIAL & CONG. COMM'N ON RISK ASSESSMENT & RISK MANAGEMENT IN REGULATORY DECISION-MAKING, 2 FINAL REPORT, *supra*.

other hand, some products may have a longer lifespan, resulting in greater probability of larger populations coming in contact with them. These parameters, among others, define the exposure factor.

Safe use of biotechnology products can be assured by adherence to risk assessment principles and development of required data using sound, science-based protocols and measurement techniques. Admittedly, there is a lack of generalized models, thus restricting risk assessment to a case-by-case analysis. Only in a few situations (i.e. *Bacillus thuringiensis*) is sufficient background information available to permit generalization and hence relaxation of information and notification requirements for field testing engineered organisms. However, the successful conduct of over 2,000 field trials over the past decade demonstrates that risk assessment is possible and has been successful.

Risk management is the next stage in the decision-making process and concerns the potential use of findings based on risk assessment.⁹⁰ Risk managers have an estimate of the magnitude of the environmental risk and must decide to what extent, if any, such risk should be controlled. What to do with GMOs after they have been subject to a risk assessment analysis would depend on applicable policy objectives relating to environmental and other socio-economic goals. Addressing the differences between risk assessment and risk management, the National Research Council (NRC) Report *Risk Assessment in the Federal Government* recommended that federal agencies should establish a strict distinction between the two processes. This advice can be written large to include international decision-making about GMOs.

Risk analysis does not offer a final and determinative answer whether GMOs advance SA. Risk assessment offers a quantitative assessment of risk based on the best available science, but the decision as to whether, or to what extent, GMOs should be regulated is a policy judgment made by risk managers. Such a determination may be based upon, but is not dictated by, scientific findings. It is therefore possible for a country to decide that GMOs should be regulated for political reasons. One reason could include the protection of local agriculture from foreign competition. However, there may be other more acceptable and persuasive reasons for doing so.

For example, the irreversibility of introducing living modified organisms into the environment, the large uncertainties about the risks of such

90. See generally William D. Ruckelshaus, *Risk, Science and Democracy*, 1 ISSUES SCI. & TECH. 19 (1985).

introductions, and the widespread human and ecological exposure to GMOs may give rise to a precautionary approach.⁹¹ Yet, at the same time, excessive precaution can suppress important benefits offered by biotechnology products, impose unnecessary costs on society, and perhaps even increase net risks as a consequence of risk-risk tradeoffs.

The National Academy of Sciences (NAS), after a study of GMOs, reported that it knew of no existing evidence that genetically modified crops posed a danger to humans via consumption.⁹² However, the NAS recommended that further study be undertaken with respect to potential impacts on the environment.⁹³ Thus, the EPA, the FDA, and the Department of Agriculture now coordinate more closely and coordinate their regulations with respect to these products.⁹⁴ Despite the generally supportive conclusions, however, both proponents and detractors of GMOs seized on the report as evidence of the correctness of their respective positions. The report is unlikely to settle the issue definitively, given the emotional nature of the issue of genetically modified food products.

*B. Precautionary Principle*⁹⁵

Does the unknown nature of the risks posed by GMOs open the door to application of the “precautionary principle” at the risk management stage? This raises the question of what is meant by the precautionary principle.⁹⁶ There is

91. Gary E. Marchant, *The Precautionary Principle: An Unprincipled Approach to Biotechnology Regulation*, 4 J. RISK RES. 143, 151-52 (2001).

92. Nat'l Res. Council, *Genetically Modified Pest-protected Plants: Science and Regulation* 8 (2002), available at <http://www.nap.edu/books/0309069300/html>.

93. *Id.* at 10-11.

94. *Id.* at 15-19.

95. While there is no authoritative legal definition of the “Precautionary Principle,” the concept of precaution, as distinct from a legal norm or term of art, is recognized in a small number of broadly adopted international, and a larger number of more restricted regional legal instruments. The broadly adopted international instruments include the following provisions: Principle 15 of the 1992 Rio Declaration on Environment and Development, June 16 1992, princ. 15, 31 I.L.M. 874, 879 (1992) (“precautionary approach”) [hereinafter Rio Declaration]; Chapter 17.22 in *Report of the United Nations Conference on the Environment and Development*, U.N. Doc.A/CONF.151/26 (1992) (“preventive, precautionary and anticipatory approaches”); the preamble in Protocol, *supra* note 7, pmbl., at 1027 (“precautionary approach”); the preamble and articles 1, 8, and 9 in Stockholm Convention on Implementing International Action on Certain Organic Pollutants, May 22, 2001, pmbl, arts. 1, 8, 9, http://www.chem.unep.ch/sc/documents/convtext/convtext_en.pdf (“precaution,” “precautionary manner”); and article 3 in United Nations Framework Convention on Climate Change, May 9, 1992, art 3(3), 31 I.L.M. 849, 854 (1992) (“precautionary measures”).

96. A perceptive commentator after a full review of the variegated uses of the term concludes that “the precautionary principle . . . is in disarray. To begin with, there is no “the” precautionary principle there.

no authoritative definition of the precautionary principle, because it keeps company with other open-textured concepts such as SD and SA. It may, however, be given a flexible definitional framework. The Preamble and Art. 1 of the Cartagena Protocol reaffirm the precautionary approach contained in Principle 15 of the Rio Declaration. According to Principle 15: "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing cost effective measures to prevent environmental degradation."⁹⁷ The Cartagena Protocol explicitly refers to the "precautionary approach," and this article will use that term interchangeably with "precautionary principle."

As implied by Principle 15, the precautionary principle would apply when there are reasonable grounds for believing that an activity or a product may cause a threat of serious or irreversible damage to health or the environment. In such cases, measures may be taken to control that activity or product in the absence of conclusive evidence establishing a causal link between that activity or product and the feared consequences. This very broad and open-textured principle has led to a variety of subjective interpretations, ranging from those based on irrational fear of the unknown to others based on science and technological risk.

An astute commentator⁹⁸ has argued that some precaution may be warranted, but criticized the application of the precautionary principle (PP) to GMOs. First, the indeterminacy of the PP makes it an inappropriate and ineffective regulatory decision-making tool. The PP provides no guidance on any of the fundamental questions that are faced in making any risk decision. The PP is ambiguous as to what level of risk is acceptable, what role costs should play in risk decisions, what quantum of scientific evidence is sufficient for making decisions, and how potential risk-risk tradeoffs should be addressed. Proponents of the PP disagree not only on these important questions, but also on whether the PP should apply in the risk assessment process, the risk management process, in both risk assessment and risk management processes, or as a substitute for the current risk assessment/risk management paradigm.⁹⁹

There are droves of differing versions, none of which is particularly helpful. . . ." Christopher D. Stone, *Is There a Precautionary Principle?* 31 ENVTL. L. REP. 10790, 10799 (2001).

97. Rio Declaration, *supra* note 95, princ. 15, at 879.

98. Gary E. Marchant, *The Precautionary Principle: Right Question, Wrong Answer*, 4 INT'L J. BIOTECH. (forthcoming 2002).

99. *Id.*

If its proponents cannot even agree on its practical meaning, the PP surely cannot provide meaningful decision-making guidance for governmental and industry risk managers who must make defensible real-world risk decisions. Especially in the United States, regulatory agencies must follow or articulate “intelligible principles” to cabin their regulatory discretion. As presently formulated, the PP offers no intelligible decision-making principle. At most then, the PP may serve as a general aspiration or goal for a regulatory system, perhaps appropriate for the preambles of international treaties and domestic statutes, but certainly not as a legally binding regulatory stricture.

The second problem with the PP is that it represents a major leap backward from a focus on risk to a focus on hazard. While used interchangeably in common parlance, “risk” and “hazard” have distinct meanings in the risk analysis literature. “Hazard” is the intrinsic potential of an agent to cause an adverse effect, whereas “risk” is the likelihood and magnitude of the adverse effect occurring under real-world exposure scenarios. While many earlier regulatory decisions were based on hazard identification, there has been increasing realization that a fuller characterization of risk usually provides a better basis for making regulatory decisions. For example, with respect to carcinogenic chemicals, agencies such as the National Toxicology Program (NTP), the International Agency for Research on Cancer (IARC), and the U.S. Environmental Protection Agency (EPA) originally classified carcinogens based only on findings of hazard (usually the results of chronic rodent bioassays). However, all of these agencies have recently recognized that exposure and mechanistic considerations can produce risk-based evaluations that are more meaningful than the original classifications based on hazard identification alone.

The PP, at least as defended by some of its strongest proponents, would appear to be directed at hazard, as opposed to risk, by calling for precautionary measures once some indicia of hazard exist. Yet every substance or product has the intrinsic potential for some hazard, which may or may not translate into real-world risks of concern. Because hazard potential is ubiquitous, basing regulatory decisions on hazard alone creates the potential for arbitrary, unfair, and inefficient regulations.¹⁰⁰ With respect to GM foods, many potential

100. According to the Codex Alimentarius Commission (CAC), a scientific body jointly established by the FAO and the WHO risk analysis consists of four steps: (1) Hazard identification, (2) hazard characterization, (3) exposure assessment, and (4) risk characterization. See http://www.foodriskclearinghouse.umd.edu/risk_analysis.htm (last visited Apr. 26, 2002).

hazards can be, and have been, hypothesized, ranging from interspecies gene transfer toxicity to non-target species to new allergens or toxins in foods. While the limited evidence supportive of these hazards may be sufficient to trigger the PP, and thus block the introduction of GM foods, there is no evidence to date demonstrating that GM foods present an actual significant risk to human health or the environment.

Another perceptive commentator disagrees with this analysis.¹⁰¹ He makes at least two points that are relevant to this article. First, he argues that it is not necessarily unwise to act solely on the basis of hazard instead of the risk. The Delaney Clause, which is triggered by hazard alone, is undesirable only because the response is an absolute ban. A statute that demanded a proportionate response to a demonstrable hazard should not be problematic. The PP, he contends, does include a proportionality requirement. Second, he argues that the PP does have a threshold requirement, at least in some formulations. They include some requirement of credible evidence and some requirement that a nontrivial harm is prevented.

The first point raises a fundamental issue as to whether the final justification for a decision should be hazard or risk. This article has argued that the justification for action to control a substance must depend on the risk it generates rather than the hazard it might pose. With regard to the second, unfortunately there is no such clarification in the Biosafety Protocol. What articles 10(6) and 11(8) state is that seeds and plants may be banned even if there is a lack of scientific certainty as to the risk posed by such seeds and plants. Given that the exporter has to undertake a scientific risk assessment, this effectively means that an importing country could ignore that risk assessment and rely on the PP to ban a product despite the absence of proven risk. Moreover, the arguments made reinforce the endemic uncertainty besetting the precautionary principle.

The finding, and particularly the mere hypothesis, of a potential hazard should not automatically necessitate a ban or other prohibition, but rather should be the impetus for additional scrutiny including data gathering, pre-market test requirements, post-market surveillance, and risk assessment. To be sure, sometimes the finding of a hazard will alone be sufficient to justify interim precautionary steps, especially when the general type of evidence produced is known to be predictive of actual risks. But the ultimate goal should

101. John S. Applegate, *The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEGAL STUD. 207 (2001).

be the assessment of real-world risks using sound science and expert judgment, critical inputs that the PP treats as dispensable.

VI. THE INTERNATIONAL LEGAL OVERLAY

A. *Potential Clashes*

Conflicts over international jurisdiction reflect interest group struggles similar to those within nation states, in which law-makers commit their countries to a variety of different and sometimes conflicting goals, objectives and programs that compete for power, ascendancy, and resources.¹⁰² In modern international society, treaties take the place of legislation. In addition, various treaties, backed by differing interest groups, demonstrate similar characteristics, and institutionalize an array of goals that deal, for example, with health, communications, welfare, transport, human rights, trade, and environmental protection. The varied goals of a pluralistic international community are potential sources of conflict. The potential clash of the SPS and Biosafety regimes illustrate this conflict.

B. *SPS Agreement*

The GATT was formed after World War II to promote world peace through equitable and efficient world trade.¹⁰³ One of the most notable GATT

102. See e.g., Cass R. Sunstein, *Beyond the Republican Revival*, 97 YALE L.J. 1539, 1542 (1988). The theoretical underpinnings of interest group politics are traversed by: ROBERT DAHL, A PREFACE TO DEMOCRATIC THEORY (1956); ROBERT DAHL, WHO GOVERNS?: DEMOCRACY AND POWER IN AN AMERICAN CITY (1961); DAVID TRUMAN, THE GOVERNMENTAL PROCESS: POLITICAL INTERESTS AND PUBLIC OPINION (1951); ARTHUR BENTLEY, THE PROCESS OF GOVERNMENT 260-61 (1967), THEODORE LOWI, THE END OF LIBERALISM: THE SECOND REPUBLIC OF THE UNITED STATES 51 (2d ed. 1979); ELMER SCHATTSCHNEIDER, THE SEMISOVEREIGN PEOPLE; A REALIST'S VIEW OF DEMOCRACY IN AMERICA (1960); LESTER W. MILBRATH, THE WASHINGTON LOBBYISTS (1963); RAYMOND BAUER, AMERICAN BUSINESS AND PUBLIC POLICY; THE POLITICS OF FOREIGN TRADE (1972); KAY SCHLOZMAN & JAMES TIERNEY, ORGANIZED INTERESTS AND AMERICAN DEMOCRACY (1986). "Public Choice" theorists attempt to take this analysis further by applying economic theory to political decisionmaking and treating the legislative process as a microeconomic system in which actual political choices are determined by the efforts of individuals and groups to further their own interests. See DENNIS MUELLER, PUBLIC CHOICE (1979); JAMES BUCHANAN & GORDON TULLOCK, THE CALCULUS OF CONSENT (1962); ANTHONY DOWNS, AN ECONOMIC THEORY OF DEMOCRACY (1957); WILLIAM RIKER, LIBERALISM AGAINST POPULISM (1982); William Landes & Richard Posner, *The Independent Judiciary in an Interest Group Perspective*, 18 J.L. & ECON. 875 (1975); Frank Easterbrook, *Statutes Domain*, 50 U. CHI. L.REV. 533 (1983). For a full review of public choice literature, see Daniel Farber & Philip Frickey, *The Jurisprudence of Public Choice*, 65 TEX. L. REV. 873 (1987).

103. Abate & Gatson, *supra* note 69, at 114.

principles relevant to environmental protection is the prohibition of protectionist activities by domestic industry, such as the imposition of bans, quotas, and licenses on imported and exported products.¹⁰⁴

The WTO came into existence in 1995 and now consists of over 130 members, accounting for over ninety percent of worldwide trade. The WTO's main objective is to help trade "flow smoothly, freely, fairly, and predictably."¹⁰⁵ The WTO encompasses the rules of GATT 1947, the Uruguay Round Protocol (Uruguay Round 1994), and the Agreement on Technical Barriers to Trade. The SPS Agreement is also a provision adopted by the WTO. The Uruguay Round attempted to liberalize international agricultural trade and open the way to a global market in which all nations, including developing nations, could compete in the production of agricultural crops.¹⁰⁶

Despite its focus on trade, the WTO recognizes the need for environmental consideration. This is reflected in its preamble and its establishment of the Committee on Trade and Environment (CTE).¹⁰⁷ However, criticism remains strong that the WTO ignores environmental concerns in favor of free trade. The power of the WTO has increasingly been criticized by many in the environmental community as a restriction on individual nation's ability to protect the environment on both a domestic and a global level.¹⁰⁸

Recognizing that some protectionist measures are necessary for health and safety reasons, the Uruguay Round incorporated the SPS Agreement.¹⁰⁹ The SPS Agreement contains measures "to protect animal or plant life or health . . . from risks arising from . . . pests, diseases, disease-carrying organisms or disease-causing organisms" and measures protecting against "additives, contaminants, toxins, or disease-carrying organisms in foods, beverages or feedstuffs."¹¹⁰ The SPS Agreement is almost always applicable to measures for the protection of biodiversity and those relating to agriculture and to agricultural biotechnology.¹¹¹

104. See generally GATT, *supra* note 6.

105. Abate & Gatson, *supra* note 69, at 115.

106. Barton, *supra* note 29, at 95.

107. GATT, *supra* note 6, at 1267-69.

108. Barton, *supra* note 29, at 100.

109. SPS Agreement, *supra* note 5.

110. Barton, *supra* note 29, at 101 (citing SPS Agreement, *supra* note 5, Annex A, art. 1).

111. Barton, *supra* note 29, at 101.

C. The Biosafety Protocol

International environmentalism and environmental protectionism, though boasting a much shorter genealogy than trade liberalization, have displayed extraordinary force and dynamism. Two notable international conferences, the Stockholm Conference on the Human Environment in 1972 (Stockholm)¹¹² and the United Nations Conference on the Environment and Development in 1992 (UNCED or Earth Summit)¹¹³ have attracted popular support far more dramatically than free trade. The surge of populism driving international environmental protection since the early 1970s coming from peoples, governments, and non-governmental organizations has resulted in an explosive growth of International Environmental Law (IEL).

The Biosafety Protocol arose out of the CBD, which was negotiated under the auspices of the United Nations Environmental Programme and was adopted on May 22, 1992. The CBD agreement entered into force on December 29, 1993.¹¹⁴ The objective of the CBD is “the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.”¹¹⁵ Article 19.3 of the CBD requires the parties to the convention to consider the need for and modalities of a protocol setting out procedures in the field for the safe transfer, handling, and use of living modified organisms (LMOs) that may have an adverse effect on biodiversity and its components.¹¹⁶ Meetings for the development of the protocol began in 1994, with the official “draft protocol” finished in February 1999 in Cartagena de Indias, Colombia.¹¹⁷

The Cartagena Protocol on Biosafety to the CBD was opened for signature on January 29, 2000 but has not yet entered into force.¹¹⁸ The stated objective of the Protocol is “to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of biotechnology that may have

112. Stockholm Declaration of the United Nations Conference on the Human Environment, June 16, 1972, 11 I.L.M. 1416.

113. Rio Declaration, *supra* note 95.

114. Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818 [hereinafter CBD].

115. *Id.* art. 1, at 823.

116. Changbo Bai, et al., Report of the Resumed Session of the Extraordinary Meeting on the Conference of the Parties for the Adoption of the Protocol on Biosafety to the Convention on Biological Diversity, 9 EARTH NEGOTIATIONS BULL., Jan. 31, 2000, available at <http://www.iisd.ca/linkages/biodiv/excop>.

117. *Id.*

118. The Protocol will come into force after the 50th instrument of ratification. Protocol, *supra* note 7, art. 37, at 1042-43. As of date, only 15 of the 109 countries who signed the treaty have ratified it. See <http://www.biodiv.org/biosafety/protocol>.

adverse effects on conservation and sustainable use of biological diversity, taking also into account risk to human health.”¹¹⁹ The Protocol generally advances this objective by adopting the precautionary principle as outlined in Principle 15 of the Rio Declaration.¹²⁰

The Biosafety Protocol applies to all LMOs and products derived there from. However, it does distinguish between products derived from LMOs that are intended to be introduced into the environment, such as seeds, fish, and microorganisms, from similar products intended to be used in food, feed, and processing.¹²¹ Products intended for introduction into the environment are subject to an Advanced Informed Agreement (AIA) procedure requiring exporters to provide certain information to and gain consent from importers prior to shipping the products.¹²² Shipments of LMOs intended for use as food, feed, or for processing are not subject to the AIA procedure, but instead are required to be labeled and documented, including labeled notification that the shipment is “not intended for intentional introduction into the environment.”¹²³

In addition to these procedures, the Biosafety Protocol establishes an Internet-based Biosafety Clearing House, where governments will post results of their domestic findings regarding biosafety and exchange scientific, environmental, technical, and legal information about products derived from LMOs.¹²⁴

D. Comparison of the Relevant Provisions of SPS Agreement and Biosafety Protocol

The following table distills the relevant provisions of the SPS Agreement and the Biosafety Protocol.

119. Protocol, *supra* note 7, art. 1, at 1027. In accordance with its article 36, the Protocol was opened for signature and as of April 2002 had been ratified by 15 nations. For more information, see Cartagena Protocol on Biosafety, <http://www.biodiv.org/biosafety> (last visited Apr. 26, 2002).

120. Protocol, *supra* note 7, art. 7, at 1030. Abate & Gatson, *supra* note 69, at 113.

121. See Protocol, *supra* note 7, arts. 7-11, at 1030-32; Abate & Gatson, *supra* note 69, at 113.

122. Protocol, *supra* note 7, art. 18, annex II, at 1035-36, 1044-45. Abate & Gatson, *supra* note 69, at 113.

123. Protocol, *supra* note 7, art. 20, at 1036-37. Abate & Gatson, *supra* note 69, at 113-14.

124. Protocol, *supra* note 7, art. 20, at 1036-37. See also Abate & Gatson, *supra* note 69, at 114.

Table 1

| | SPS Agreement | Biosafety Protocol |
|---------------------------|--|--|
| Scope | Protect health of humans, animals and plants | Protect against LMOs causing adverse effects. Conservation and sustainable use. Employ Precautionary Principle |
| Objectives | Prevent arbitrary and unjustifiable discrimination; and/or disguised restrictions on international trade | Ensure adequate levels of protection against LMOs resulting from modern biotechnology |
| Burden of Proof | On importer | On exporter |
| Basis for Decision | Objective: Based on: international standards [art. 3(1)], scientific justification [art. 3(3)], or risk assessment [arts. 3(3) & 5(1-8)] | Subjective: FOOD: Domestic regulatory framework [art. 11(4)]; or risk assessment in absence of domestic regulation [art. 11(6) (a)]. SEEDS & PLANTS: risk assessment but lack of scientific certainty due to insufficient scientific information no bar to prohibiting imports [art. 10(6) & art. 11(8)] |
| Risk Assessment | Undertaken by importer. Taking account of risk assessment techniques developed by relevant international organizations.[art. 5(1)] | Costs borne by exporter [art. 15(3)]. FOOD: risk assessment by exporter [art. 11(1) & annex II]. Required by importer only if there are no domestic regulations. SEEDS & PLANTS: risk assessment required under article 15. |
| Risk Management | Not required | Establish regulations to manage and control risks in handling and transboundary movement of LMOs |
| Harmonization | Mandatory. Measures shall be based on international standards and guidelines [art. 3(1)]where available | Discretionary. "Encouraged" to "take account" "as appropriate" of international standards [art. 2(5)] |
| Equivalence | Mandatory. Members shall accept the SPS of other members as equivalent even if there are differences, if exporters SPS measures achieve appropriate level of protection. [art. 4(1)] | Liberty of importing state to disregard equivalence. |

In light of the alleged risks posed by GMOs, the most crucial question is whether GMOs affect the health of humans, animals, and plants. Under the SPS Agreement, the country seeking to restrict trade in GMOs carries the burden of proving such harm with scientific risk assessments.

The requirement that SPS measures be based on international standards attempts to remove discrimination on subjective grounds. The equivalence provisions contained in article four recognize that prior to their export, GMOs have already been subjected to national tests and regulations to prevent adverse environmental impacts.¹²⁵

E. Avoiding Conflict

The usual way of avoiding potential conflicts between two treaties is for one of them to give priority to the other. A treaty is similar to a contract, and it is a time-honored instrument for reducing a prior agreement into writing. It is a vehicle for reflecting agreement, not for registering disagreement or differences between its parties. The Biosafety Protocol, however, makes a travesty of international law. If, as it is abundantly clear, the parties to the Biosafety Protocol were unable to agree on the priority or precedence of the Biosafety Protocol over other trade treaties, they ought to have recognized their disagreement during the negotiating process, but refrained from using the Protocol to publicize their differences. Instead, they chose to denigrate the institution of treaty making by making an inexplicable international exhibition of their dispute.

The preamble to the Cartagena Protocol begins by “recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development.”¹²⁶ Immediately after this incantation, it engages in a display of legal chicanery: “[e]mphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements, Understanding that the above recital is not intended to subordinate this Protocol to other international agreements . . .”¹²⁷

Clearly, some negotiators wanted the Cartagena Protocol to be subject to existing WTO agreements, a view embodied in the first part of the quotation. Not to be outdone, those who objected to the trumping of the Cartagena

125. Protocol, *supra* note 7, art. 4, at 1029.

126. Protocol, *supra* note 7, pmb., at 1027.

127. *Id.*

Protocol insisted that any such recital is not intended to subordinate the Protocol to prior agreements. Consequently, the Cartagena Protocol is a corrupted treaty that adopts the impossible and absurd position of both affirming and rejecting earlier obligations.

F. Dispute Resolution

The substantive provisions of a treaty, however formidable, can remain ineffectual absent a system of compulsory adjudication. The international legal system does not possess a universal system of compulsory and binding dispute settlement, and many international treaties are sadly lacking in judicial enforcement. Consequently, nations and international organizations are obliged to rely for treaty implementation upon diplomatic negotiations and other methods of dispute resolution. The absence of compulsory judicial institutions is fast becoming recognized as a serious weakness in the embryonic legal system prevailing in the international community.

In the years following World War II, GATT, and its successor WTO, have aspired to be the sole arbiter of all disputes relating to international trade. Until 1994, however, the decisions of the prevailing panel system required affirmative approval by the GATT and were subject to single member veto power. Judicial hegemony was greatly advanced by the 1994 Understanding on the Settlement of Disputes (DSU),¹²⁸ which established a judicial-type dispute settlement system. This contrasts with the earlier, less binding, more consensus-oriented system under the GATT. The DSU ensures that all dispute settlement procedures under the GATT, the Subsidies Code, and a variety of other trade related agreements (Covered Agreements)¹²⁹ are brought within a single dispute resolution process overseen by the Dispute Settlement Body (DSB).¹³⁰ If parties are unable to reach a consensual negotiated settlement of

128. *See generally* Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, GATT, *supra* note 6, Annex II, at 1226 [hereinafter DSU]. It consists of 27 articles and 4 appendixes. *Id.* The purpose of the WTO dispute settlement system is to confer predictability and security of outcome in an international legal order that is lacking such attributes. *Id.*, art. 3, para. 2, at 1227.

129. *See id.*, art. 1, at 1226.

130. *See id.* art. 2, at 1226-27. This ends the potential for forum shopping that existed within the old GATT. The heart of the new system is the DSB, which is authorized to establish panels, adopt panel and appellate reports, maintain surveillance of implementation of rulings and recommendations, and authorize retaliatory measures in cases where states do not implement panel recommendations. *See generally id.* (laying out the procedures by which disputes are settled).

Although more judicial than GATT, the new WTO procedures are subject to legally possible, though politically difficult, countermand at every critical stage in the procedure. There is no affirmative approval

their dispute, a Panel is set up to hear the case. The findings of the Panel, subject to appeal, are accepted by the Dispute Settlement Body, and are binding on the parties.

The law applied by GATT/WTO is confined to that found in its own treaties and does not recognize any broader corpus of general international law, let alone IEL.¹³¹ Since environmental protection has never been and is not a GATT/WTO objective, the GATT and its Covered Agreements do not address environmental protection, apart from the exceptions found in article XX of GATT 1947, the TBT and SPS Agreements. It is abundantly clear that the GATT/WTO Panels and Appellate bodies must restrict themselves to the Understanding and the Covered Agreements,¹³² which, moreover, should be interpreted and construed strictly in a way that does not add to or diminish the rights and obligations provided by the treaties.¹³³

Because of their institutional and legal prominence, GATT panels, and the new, stronger DSB, have emerged as the sole legal forum for resolving many disputes in which the goals of environmental protection and free trade are in conflict. Environmentalists have feared this assertion of jurisdiction by GATT/WTO.¹³⁴ First, as described above, the substantive law of GATT/WTO

requirement, or a single member veto power, as existed under the old GATT procedures. However, each step in the process of setting up panels, along with their adoption and implementation, can be countermanded by a negative consensus decision by the DSB.

The dispute settlement procedure is activated by a request from a member state, whereupon the DSB, in the absence of a consensus decision not to do so, establishes a well-qualified panel to hear the case. The panel examines the matter in light of the relevant provisions of the covered agreements cited by the parties to the dispute. After careful consideration, the panel submits its findings in a report to the DSB. This report will be adopted by the DSB unless: 1) A party to the dispute formally appeals the panel decision, or 2) the DSB decides by consensus not to adopt the report. Where there is an appeal and the Appellate Body upholds the legal findings and conclusions of the panel, its report shall be adopted by the DSB, unless the DSB decides by consensus not to adopt the decision.

131. *See id.*, art. 3, para. 1, at 1227.

132. *See id.* art. 3, para. 4, at 1227 ("Recommendations or rulings made by the DSB shall be aimed at achieving a satisfactory settlement of the matter *in accordance with the rights and obligations under this Understanding and under the covered agreements.*") (emphasis added). *See also id.* art. 3, para. 5, at 1227. "All solutions . . . shall be consistent with those agreements, and *shall not nullify or impair benefits accruing to any Member under those agreements, nor impede the attainment of any objective of those agreements.*" *Id.* (emphasis added). Article 7 deals with the terms of reference of Panels and confines them to "[t]he relevant provisions in any covered agreement or agreements cited by the parties to the dispute." *Id.* art. 7, para. 2, at 1231. Article 11 deals with the functions of panels and requires them to assess the "[a]pplicability of and conformity with the relevant covered agreements." *Id.* art. 11, at 1233. There is no reference to any other laws or principles.

133. *Id.* art. 3, para. 2, at 1227. It states conclusively that "recommendations and rulings of the DSB *cannot add to or diminish the rights and obligations provided in the covered agreements.*" *Id.* (emphasis added).

134. The fuller arguments are delineated in Lakshman Guruswamy, *The Promise of UNCLOS: Justice in Trade and Environment Disputes?*, 25 *ECOLOGY L. Q.* 189 (1998) (arguing international environmental law

ignores international law pertaining to environmental protection and treats any law or treaty not embodied in GATT or its "covered agreements"¹³⁵ as irrelevant.¹³⁶ Second, the track record of GATT litigation demonstrates the extent to which international environmental protection has been diminished. I have argued elsewhere that GATT panels view IEL trade restrictions as obstructions to the legal regime created by the GATT/WTO and have sought to liberalize trade by eliminating environmental controls and restrictions.¹³⁷ Furthermore, the judges who interpret such substantive trade law are unfamiliar with, if not unfriendly toward, laws and agreements directed at international environmental protection.¹³⁸ Third, GATT/WTO judges are prevented from engaging in the customary judicial role of interpreting and developing the law.¹³⁹

G. Fair and Reasonable

The domain of international law, once perceived as consisting only of legally sovereign nations, is quickly becoming a shrinking, interconnected, and transnational world of global trade and technology that reaches beyond national boundaries. The actions of corporations, individuals, and groups engaged in trade, commerce, and cultural, social, and economic interactions often subject those entities to the laws of more than one country, and therefore to the competing or complementary jurisdiction of the forums within those countries. This is not surprising, as many nations exercise concurrent jurisdiction over areas of public law that are common to all nations and peoples, such as health, safety, trade, economic regulations, communications, technology, and the environment.¹⁴⁰ Increasing international litigation reveals the extent to which

need not be conducted under the umbrella of the WTO). See also Guruswamy, *Should UNCLOS or GATT/WTO Decide*, *supra* note 8 (asserting that the UNCLOS provides a viable and more suitable forum for the settlement of environmental trade disputes).

135. See DSU, *supra* note 128, art. 1, at 1226.

136. See Lakshman Guruswamy, *The Annihilation of Sea Turtles: World Trade Organization Intransigence and U.S. Equivocation*, 30 ENVTL. L. REP. 10261 (2000).

137. See Guruswamy, *Should UNCLOS or GATT/WTO Decide*, *supra* note 8.

138. *Id.* at 319.

139. *Id.* at 319-21.

140. U.S. cases dealing with overlapping jurisdiction have addressed economic regulations dealing with bank secrecy, *United States of America v. First Nat'l City Bank*, 396 F.2d 897 (2d Cir. 1968), and the law applicable to air transportation, *Laker Airways Ltd. v. Sabena, Belgian World Airlines & KLM Royal Dutch Airlines*, 731 F.2d 909 (D.C. Cir. 1984).

the world's national legal systems are clothed with concurrent, not exclusive, jurisdiction.¹⁴¹

Many domestic courts, when relying on principles of international law, have used fairness and reasonableness as the primary criteria for asserting jurisdiction.¹⁴² Furthermore, some commentators have argued that conflict of laws principles are principles of international law, since conflict of laws is part of the law of nations.¹⁴³ This claim has garnered considerable judicial support, as it has a long and distinguished lineage originating with the sixteenth- and seventeenth-century writers on international law, including Grotius.¹⁴⁴ The cogency of this reasoning becomes evident when we consider the fact that courts are the organs of government, and that international law should determine jurisdiction over the respective merits of competing claims by nations and governments.

A plethora of conflicts theories attempt to articulate the restraining or constraining principles that should guide a court in deciding whether or not to exercise its jurisdiction.¹⁴⁵ They include vested rights,¹⁴⁶ interest analysis,¹⁴⁷

141. See generally, GARY B. BORN, *INTERNATIONAL CIVIL LITIGATION IN UNITED STATES COURTS* (3d ed. 1996).

142. See ANDREAS F. LOWENFELD, *INTERNATIONAL LITIGATION AND THE QUEST FOR REASONABLENESS* (1996). Professor Lowenfeld offers numerous cases supporting his thesis that there is an emerging consensus that fairness and reasonableness be used as the criteria employed in asserting both legislative and judicial jurisdiction. He argues that these cases display a confluence between national and international criteria based on fairness and reasonableness. *Id.* at 79. In *Bier v. Mines de Potasse d'Alsace SA*, 1976 E.C.R. 1735, a French company in Alsace discharged massive amounts of chlorides into the Rhine. The chloride allegedly damaged nursery gardens in Holland and the Dutch Supreme Court upheld the assertion of jurisdiction by a Dutch court despite the pleas that the discharge of applied Dutch, basing itself on a EEC Convention on jurisdiction and the enforcement of judgments. Subsequently, a Dutch law concerning environmental damage, rejecting the defense that the conduct was lawful. LOWENFELD, *supra*, at 30. In another case, *Muduroglou Ltd. v. TC Ziraat Bankasi*, [1986] 3 W.L.R. 606, *Muduroglou*, a construction company incorporated in northern Cyprus sued a Turkish Bank for \$20 million, claiming the Turkish bank had wrongfully paid this to the Libyan government. *Muduroglou* first sued in England, but the courts rejected jurisdiction on the basis of *forum non conveniens*. *Muduroglou* then tried Germany claiming that a German statute gave the German courts jurisdiction. The German Supreme Court found that the statute should be read in conjunction with the international competence (or jurisdiction) of the German courts, and held that the necessary link required by international law was not present. LOWENFELD, *supra* at 59-61. In a third case, *Goto v. Malaysian Airline System* 35 Minshu 1224 (Sup. Ct., Oct. 16, 1981), a Japanese widow whose husband was killed in Malaysia in an airline crash, sued the Malaysian airline for non performance of the contract of carriage. The Malaysian airline which maintained an office and did business in Japan moved to dismiss the suit on the basis that the contract of carriage was entered into in Malaysia and bore no relation to the business in Japan. The Japanese Supreme Court applied the principle of fairness and found that it possessed jurisdiction. LOWENFELD, *supra* at 48-51.

143. See LOWENFELD, *supra* note 142, at 3.

144. See Michael Akehurst, *Jurisdiction in International Law*, BRIT. Y.B. INT'L L. 145, 213 (1973) (citing Max Rheinstein, *The Constitutional Bases of Jurisdiction*, 22 U. CHI. L. REV. 775, 802-17 (1955)).

145. See generally LEA BRILMAYER, *CONFLICT OF LAWS* 1-125 (1995).

comparative impairment,¹⁴⁸ a “better law” approach,¹⁴⁹ the most significant relationship,¹⁵⁰ and comity.¹⁵¹ It is not necessary to choose between these theories as they can be distilled, in the final analysis, to require simply that the court find a principled and reasoned basis for its decision. In essence, a court clothed with legislative jurisdiction must exercise its judicial jurisdiction in a manner that is both politically fair¹⁵² and reasonable.¹⁵³

Judge Fitzmaurice encapsulated such a view in his separate opinion in the *Barcelona Traction* case:

[I]nternational law does not impose hard and fast rules on States delimiting spheres of national jurisdiction. . . . It does however . . . involve for every State an obligation to exercise moderation and restraint as to the extent of the jurisdiction assumed by its courts in cases having a foreign element, and to avoid undue encroachment on a jurisdiction more properly appertaining to, or more appropriately exercisable by another state.¹⁵⁴

The Restatement (Third) of the Foreign Relations Law of the United States lists a number of factors that might guide courts in determining what is fair and reasonable.¹⁵⁵

It is possible to view these conflict of laws rules not only as rules of customary international law, but also as “general principles of law recognized

146. See *id.* (citing JOSEPH BEALE, A TREATISE ON THE CONFLICT OF LAWS (1935)).

147. See *id.* (citing BERNARD CURRIE, SELECTED ESSAYS ON THE CONFLICT OF LAWS (1963)).

148. As expounded by William Baxter, *Choice of Law and the Federal System*, 16 STAN.L. R. 1 (1963).

149. Advocated by Robert Lefflar, *Conflicts Law: More on Choice Influencing Considerations*, 54 CAL. L. REV. 1584 (1966).

150. As expressed in the RESTATEMENT (SECOND) OF CONFLICT OF LAWS § 6 (1971).

151. See Joel R. Paul, *Comity in International Law*, 32 HARV. INT'L L.J. 1 (1991).

152. See LEA BRILMAYER, CONFLICT OF LAWS 236-37 (1995).

153. See RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 403(1) (1987).

154. *Barcelona Traction, Light & Power Company Case (Belgium v. Spain)*, 1970 I.C.J. 3, 105.

155. They include (a) the link of the activity to the territory of the regulating state; (b) connections such as nationality, residence, or economic activity; (c) the character of the activity to be regulated and its importance to the regulating state; (d) the existence of justified expectations that might be protected or hurt by the regulation; (e) the importance of the regulation to the international, political, legal, or economic system; (f) the extent to which the regulation is consistent with the traditions of the international system; (g) the extent to which another state may have an interest in regulating the activity; and, (h) the likelihood of conflict with regulation by another state. RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 403(2) (1987).

by civilized nations" under article 38(c) of the Statute of the International Court of Justice. Even if they are not determinative and binding as general principles of international law, conflicts of laws principles are rationally compelling and legally persuasive, and it is to those principles that we now turn.

The cardinal rules of fairness and reasonableness are expressed through supplemental doctrines such as comity,¹⁵⁶ forum non conveniens,¹⁵⁷ and choice of law.¹⁵⁸ Consequently, reasonableness and fairness enjoy a dual legal character. They are rules of customary international law governing jurisdictional claims among domestic tribunals, and also general principles of law applicable to intergovernmental tribunals.

H. Is Risk Assessment Fair and Reasonable?

I have noted that the DSB of the WTO is clothed with exclusive jurisdiction in cases involving potential conflicts between the SPS Agreement and the Biosafety Protocol. It is important, however, to ascertain whether the law administered by the DSB in such cases will be fair and reasonable, especially in light of the fact that past decisions of the GATT/WTO in trade versus environment cases have given rise to legitimate grievances about unfair and unjust results.

It behooves us, however, to judge each case on its merits. If a case filed under the DSU might involve a substantive conflict between the SPS Agreement and the Biosafety Protocol, it is important to determine if DSU will apply fair and reasonable principles. In light of the foregoing discussion, I conclude that the risk assessment procedures under the SPS are fair and reasonable and are qualitatively superior to the precautionary principle embodied in the Biosafety Protocol. Given the enormous beneficial impact

156. Comity mitigates the conflicts between competing international forums and mediates differences between legal systems. In the case of *Hilton v. Guyot*, 159 U.S. 113, 163-164 (1895), the court stated:

"Comity," in the legal sense, is neither a matter of absolute obligation, on the one hand, nor of mere courtesy and good will, upon the other. But it is the recognition which one nation allows within its territory to the legislative, executive, or judicial acts of another nation, having due regard both to international duty and convenience, and to the rights of its own citizens or of other persons who are under the protection of its laws.

157. The doctrine of forum non conveniens was succinctly described by Paxton Blair in his classic article as "the discretionary power of a court to decline to exercise a possessed jurisdiction whenever it appears that the cause before it may be more appropriately tried elsewhere." Paxton Blair, *The Doctrine of Forum Non Conveniens in Anglo-American Law*, 29 COLUMB. L. REV. 1, 1 (1929).

158. This doctrine addresses the question of "which jurisdiction's laws should apply in a given case." BLACK'S LAW DICTIONARY 234 (7th ed. 1999).

GMOs can have on developing countries, it would be regressive to attempt to impede their access into those countries under the Biosafety Protocol. Furthermore, it is likely that the so-called precautionary principle could be used as a subterfuge to erect unfair and unscientific trade barriers.

The decision of the Appellate Body of the WTO in the Beef Hormone case¹⁵⁹ demonstrates the extent to which risk assessment can emerge as both reasonable and fair. The Beef Hormone dispute involved several European Community directives forbidding the importation of U.S. beef treated by natural and artificial growth-enhancing hormones. While the European Community claimed that its directives met the SPS Agreement standards, the United States asserted that the European Community had not adduced any evidence to demonstrate the existence of a bona fide risk to human health from the use of the six hormones in question.¹⁶⁰

In its Appellate Body report, the WTO established that countries desiring to impose an SPS measure could do so under article 3.3 of the SPS accord. A member may go beyond an existing international standard, without even the pretense that its measure is “based on” an international level of protection.¹⁶¹ In this latter case, however, members must show that their election of a more stringent standard is scientifically justified.¹⁶² Scientific justification exists if a Member determines, based on “available scientific information,” that the international standard in question is insufficient to achieve the state’s chosen level of protection.

Contrary to the EC’s wishes, the WTO Appellate Body drew the conclusion in the Beef Hormone case that when a nation elects to go beyond an established international standard, it must under SPS Agreement article 5.1 and paragraph 4 of annex A, conduct a risk assessment.¹⁶³ The Appellate Body, just like the lower WTO Panel, felt that the precautionary principle, even if proven to be a part of customary international law, could not override the explicit provisions of 5.1 and 5.2 of the SPS.¹⁶⁴ Indeed, the Appellate Body expressed doubt as to whether the precautionary principle was in fact a principle of customary

159. WTO Appellate Body Report on EC Measures Concerning Meat and Meat Products (Hormones), Jan. 16, 1998, WT/DS48/AB/R, at http://www.wto.org/english/docs_e/docs_e.htm.

160. *See id.*

161. *Id.* ¶ 172.

162. *See* SPS Agreement, *supra* note 5, art. 3.3.

163. WTO Appellate Body Report on EC Measures Concerning Meat and Meat Products (Hormones), *supra* note 159, ¶¶ 175-76.

164. *Id.* ¶¶ 120, 125.

international law or a general principle of law under article 38(c) of the Statute of the International Court of Justice.¹⁶⁵

CONCLUSION

Environmentalists have had good reason to be aggrieved by past DSB decisions. In light of the unfairness demonstrated by the DSB, I have argued that cases involving potential conflicts between international environmental law and international trade law should be decided not by the DSB, but by other tribunals, notably under the United Nations Law of the Sea Convention.

It is possible that the DSB may be changing. For example, in the Shrimp case, the Appellate Body appeared to recognize the existence of multilateral environmental instruments.¹⁶⁶ Moreover, the Beef Hormone case opened the door to international law by considering whether the precautionary principle was a part of customary international law. Whether the DSB will more generally recognize international environmental law remains to be seen, and environmentalists have reason to be skeptical. A conflict between the SPS Agreement and the Biosafety Protocol, however, is not one that pits environmental policies against antithetical rules of free trade.

This article has suggested that there are two principles of customary international law relevant to adjudications involving concurrent or complementary jurisdiction: fairness and reasonableness. According to the Restatement (Third), reasonableness is a rule of customary international law applicable to domestic courts.¹⁶⁷ While these principles enjoy the status of custom they also qualify as cardinal general principles of law applicable to intergovernmental tribunals. It has also sought to establish that GMOs do advance SD, and can make a substantial contribution to food security in developing countries. The SPS Agreement, which seeks to reduce the number of arbitrary and questionable trade barriers ostensibly established for health and safety reasons, strikes the right balance. The kind of risk assessment it requires advances fairness and reasonableness in a way that the precautionary principle does not.

165. *Id.* ¶ 123.

166. *United States-Import Prohibition of Certain Shrimp and Shrimp Products*, Oct. 12, 1998, ¶¶ 166-171, WT/DS58/AB/R, reprinted in 38 I.L.M. 118 (1999).

167. See *infra* note 10.

Two caveats are in order. First, the fact that the DSB may have it right on this occasion does not mean that it will act fairly or reasonably in other cases involving clashes between free trade and environmental protection. Second, the fact that the United States and other developed countries produce an abundance of food does not mean that this food is available to the poor, starving, and dying who live in the undeveloped or developing countries of the world. Justice and equity demand that we address this problem. Food assistance such as that offered by the developed countries to poorer countries at best offers a Band-Aid solution. Such aid, moreover, is dependent on fickle politics that may change with changes in governments.

A more permanent and satisfactory solution is for developing countries to increase agricultural yield. But increased food production does not mean that such food will be distributed. Welfare inequity is as much a national as an international problem. Difficulties surrounding the efficient distribution of food are compounded by the fact that many developing countries lack basic transport and administrative infrastructures. Finally, even if the developing countries of the world achieve political Nirvana, they will still be left with intractable problems of geography, climate, and soil that do not admit of political solutions.